REMARKS

Claims 1-9 were originally pending in the present application. Claims 1-5 were cancelled in a previous Response, leaving Claims 6-9 pending and at issue. Of the remaining claims, Claim 6 has been amended to place the claims in better condition for allowance. Particularly, Claim 6 has been amended to clarify that the effective amount of N-acetyl-D-glucosamine or pharmaceutically acceptable salts thereof is the only active agent in the composition.

The pending claims stand rejected under 35 USC 103(a) as unpatentable over Adalsteinsson et al. (WO 01/19374) in view of Burton et al. (US 5,217,962). Applicant disagrees with this rejection and requests reconsideration in view of the above amendments and remarks below.

With respect to Adalsteinsson, the Examiner contends:

> Adalsteinsson teaches the use of a composition comprising glucosamine for the treatment of autoimmune diseases like Graves disease (same as hyperthyroidism) and erythematosus and psoriasis using glucosamine. According to Adalsteinsson eheumatoid arthritis is an autoimmune disease and its etiology is much the same as that of any other autoimmune disease (page 1, lines 13-16; page 3, line 24 through page 3, line 6; page 8, line 20 through page 10, line 3). Salt forms of the active agent can also be used (page 14, lines 9-11) and the compositions can be prepared for other forms of administration (page 21, line 16 through page 22, line 13). Adalsteinsson et al do not exemplify or teacht eh use of N-acetyl-D-glucosamine for the treatment of the diseases as instantly claimed. However, one of skill in the art wil recognize from this teaching that an active agent containing the glucosamine moiety can also be used for the treatment of diseases like erythematosus and hyperthyroidism.

As to Burton, it is the Examiner's position that:

> Burton et al. teach the oral administration of N-acetyl glucosamine for the treatment of psoriasis (a local lesion). The dosage is about 300 mg to 10,000 g per day (col. 2, line 52 through col. 3, line 3; col. 8, lines 30-46) and the active agent can be incorporated in a pharmaceutically acceptable carrier. Even though Burton does not specifically teach the use of N-acetyl glucosamine for the treatment of erythematosus and hyperthyroidism, Adalsteinsson teaches that in addition to rheumatoid arthritis, autoimmunity often results in diseases like Graves disease (same as hyperthyroidism) and erythematosus and psoriasis (Adalsteinsson, page 4, lines 3-6). Hence, one of skill in

the art will recognize from the teaching of Adalsteinsson and Burton that N-acetyl-D-glucosamine can also be used for the treatment of erythematosus and hyperthyroidism (Graves disease).

Applicant contends the Burton is directed to treatment using the combination of hyperimmunized egg product and glucosamine (see page 13, lines 22-24 and the issued claims), while the present invention uses only N-acetyl-D-glucosamine or pharmaceutically acceptable salts thereof as the active agent. It can not be expected that the effect of a combination containing two active agents can be achieved by use of only a single compound being somewhat similar to one active agent of the combination. Further, Burton only discusses the use of glucosamine and its salts, such as glucosamine HCL and glucosamine sulfate, for use in the combination. Burton never mentions the use of glucosamie derivatives, particularly the use of N-acetyl-D-glucosamine. The active agent of the present invention, N-acetyl-D-glucosamine, is different in molecular structure from glucosamine.

The inventors of the present invention first found that N-acetyl-D-glucosamine has a function for promoting bio-waves, and was further effective for treating and controlling lupus erythematosus and hyperthyroidism. One skilled in the art would not recognize from Burton the technical solution of the present claims.

As to the obviousness-type double-patenting rejection, applicant contends that the amendments further distinguish over the claims of co-pending Application No. 10/550,784. However, should the Examiner maintain this rejection, Applicants are prepared to file a terminal disclaimer as a means to obviate the provisional rejection, in the event allowance of the pending claims is received.

CONCLUSION

Applicant contends that all claims are in condition for allowance. Applicant requests that, should the Examiner maintain the present rejections, the present amendments be entered to place the application in better condition for appeal.

Should any formalities remain which can be corrected by Examiner's amendment, Applicant requests that the undersigned be contacted by phone in order to expedite the prosecution of the present case.

Respectfully submitted,

By _____

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